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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,552	09/15/2003	Xiaohui Zhang		2279
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/662,552	ZHANG, XIAOHUI			
		Examiner	Art Unit			
		Neal R. Sereboff	3626			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
• •						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status			•			
1)⊠)⊠ Responsive to communication(s) filed on <u>27 April 2007</u> .					
2a)⊠	This action is FINAL . 2b) ☐ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	ion of Claims					
4)⊠	4)⊠ Claim(s) <u>1-15</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.					
•	Claim(s) <u>1-15</u> is/are rejected.					
·	Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	ion Papers					
9)□	The specification is objected to by the Examine	r.				
10)	The drawing(s) filed on is/are: a) _ acce	epted or b) objected to by the	Examiner.			
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority (ınder 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
		•				
Attachment(s)						
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D				
3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6)						

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DETAILED ACTION

Response to Amendment

1. In the amendment filed 4/27/2007 the following has occurred: Claims 1 - 13 and 15 have been amended. Now claims 1 - 15 are presented for examination.

Notice to Applicant

- 2. Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.
- 3. Within the Office Action dated 12/19/2006, page 2, the Examiner suggested that the applicant review MPEP §608.01 (n). For the Applicant's convenience, (c) is included here: "One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(j). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by

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reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered."

Claim Objections

4. Claims 4 – 6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4 – 6 have not been further treated on the merits.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 6. Claims 1 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
- The result of the instant invention is one or more numbers, generated by a human being. The numbers generated by the individual might be considered "useful" in the sense that the numbers may be used to determine epidemics. However, §101 requires that the results be reproducible. In the instant case, the model describing the categorized public health status is the result of subjective feelings about rule system components. Even that same person might generate different results at different times for the same conditions, as when the person might feel differently about the conditions at a later time. Moreover, since the result is subjective and dependent on a cognitive process, a person can be dishonest about how the person actually thinks a condition should be weighted, and generate any number within a given rule system. The subjective component of the invention is not amenable to reproducibility of a result. In any

event, the result is not concrete or tangible, but merely one or more numbers that may serve as input data for processing and use in a system not claimed.

8. Claim 1 recites no particular implementation of the idea of a rule system. The claim may require no more than presenting a number, reviewing the number, and an individual ruling upon the image mentally, or orally, or recording the rule result on a piece of paper, or having the rule result entered into a machine (not claimed) in a further process step (not claimed). The instant claims represent a disembodied "abstract idea." All of the claims are thus drawn to the abstract idea of a rule system, rather than to a practical application of the idea as required by 35 U.S.C. §101.

Claim Rejections - 35 USC § 112

- 9. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 10. Claims 1 15 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based first upon the Background of the Invention describing how the inventor's invention overcomes existing problems. Second, evidence of concealment is further shown in that one of ordinary skill in the art could not perform this invention because of the absence of both a method of practicing the invention within the written description and also the lack of a working example within the written description.
- 11. Claims 1 15 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. A computerized system is critical or essential to the practice of the

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invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). As described, the application does not provide any structural implementation of the algorithm.

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- 12. Claims 1 - 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The broad breadth of the claims and lack of detail within the written description provides no instructions on practicing this invention. The disease control nature of the invention requires that proper practice of the invention is necessary. Although the prior art is developed, the inventor states within the background that his invention overcomes missing systems. One of ordinary skill in the art requires a high amount of mathematical knowledge as evidenced by both the written description and also Goldenberg et al., "Early statistical detection of anthrax outbreaks by tracking over-thecounter medication sales" (see reference U on the attached PTO-892). The well developed prior art is explicitly differentiated by the inventor however the written descriptions provides no direction or assistance through either working examples or instructions. This lack of details makes a large amount of experimentation necessary. Therefore, one of ordinary skill in the art at the time the invention was made would not be enabled to make or use this invention.
- 13. Claims 1 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. The addition of "apparatus" to the independent claim constitutes new matter because no device or apparatus was described within the application as originally filed.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 15. Claims 1 15 are rejected as failing to define the invention in the manner required by 35
 U.S.C. 112, second paragraph.
 - a. Claim 1 recites the limitation "rule system" in lines 23, 25, 30, and 33. There is insufficient antecedent basis for this limitation in the claim. The examiner notes that the definite article "the" is used to refer back to a previous object occurrence while the indefinite articles "a" or "an" are used to for the initial object occurrence. The examiner is not sure whether "the rule systems" on line 23 is a combination of the three "a rule system" described on lines 25, 30 and 33 respectively. Further, the examiner cannot determine to which "rule system" claims 2 6, 10 and 13 15 refer.
 - b. Claim 1 recites the limitation "public health status" within the preamble lines 1 and 2. Claim 1 then refers to a public health status on lines 8, 13, 14 and 18. The multiple health status cause the exact public health status to be unknown. Claims 2 15 are rejected as being further dependent upon claim 1.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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1. Claims 1 – 5, 7, 10 – 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg et al., "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales" (see reference U on the attached PTO-892).

- 2. As per claim 1, Goldenberg teaches the apparatus for detecting an unusual public health status and for modeling the change of categorized public health status from over-the-counter (OTC) pharmaceutical sales data, comprising an apparatus (see concluding remarks paragraph 5) with:
 - A measurement scheme defined by a set of variables and calculations of categorized daily
 OTC sales data in a specified geographical scale (see page 2, Tracking Grocery Data section, paragraph 1 where geographical scale is noted by address)
 - An algorithm for unusual public health status (or event) detection incorporating seasonally varying reference lines (see page 2, Tracking Grocery Data section, paragraph
 5), and calculating three structural components from the input data:
 - o A daily deviation from the reference line, (see Figure 3)
 - o An n-days-cumulated-deviation, and (see Figure 3)
 - o The change of the daily deviations in that area, (see Figure 3)
 - A dynamic system model describing the categorized public health status by a set of state variables, and the change of the public health status by state transition, input sets, output sets, and rule systems that govern them (see page 3, paragraph 1),
 - A rule system determines the state transitions for modeling the dynamic change of public health status through the analysis of information derived from OTC pharmaceutical sales in that area (see page 3, paragraph 1),

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 A rule system combines the structural components incorporating the confidence supporting sets as the input variables (see page 3, paragraph 2 where the confidence arises by defining the input boundaries),

- A rule system maps the state history to the output variables (see figure 5 where state history is determined by the amount of antibiotic being purchased).
- 3. As per claim 2, Goldenberg teaches the apparatus of claim 1 as described above. Goldenberg further teaches the apparatus wherein said measurement scheme includes the calculation of monthly (or weekly, or daily, or seasonally) averaged daily sales for the categorized OTC medicines as a base line, from the data in the past at the same place, which is one data set (base line) for supporting the rule system (see figure 1).
- 4. As per claim 3, Goldenberg teaches the apparatus of claim 2, as described above. Goldenberg further teaches the apparatus wherein said measurement scheme includes the calculation of the deviation of daily sales in the current-month from the base line, and it is measured in change of percentage at the same place, which is another data set (the first structural component) for supporting the rule system (see figure 3).
- 5. As per claim 7, Goldenberg teaches the apparatus of claim 1 as described above. Goldenberg further teaches the apparatus wherein said dynamic model of the categorized public health status is defined by the system with a set of state variables and state transitions over the time dimension at a specified place, with which state transitions model the change of the categorized public health status in that place (see page 2, Tracking Grocery Data section, paragraph 1 where the state variables and public health are tracked through antibiotic sales).

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6. As per claim 9, Goldenberg teaches the apparatus of claim 1 as described above. Goldenberg further teaches the apparatus wherein said state transitions over time at a specified place, further comprising a mathematical descriptions on how the categorized health status changes from one state variable to another state variable as time advances. The example time unit is daily (see figure 5).

- 7. As per claim 10, Goldenberg teaches the apparatus of claim 1 as described above. Goldenberg further teaches the apparatus wherein said input variables are the mapped supporting sets for the state transition rule systems (see page 1 paragraph 3); the structural components are mapped from incorporating their confidence levels (see figure 2 and page 3 paragraph 2 where statistical quality control creates confidence levels).
- 8. As per claim 11, Goldenberg teaches the apparatus of claim 10 as described above. Goldenberg further teaches the apparatus where the mapped confidence levels are derived from the historical data sets (see page 3 paragraph 2 where the historical data sets are the natural variation), and the confidence supporting sets are found from the cumulated distribution functions with the specified confidence levels (see figure 3 and page 3 paragraph 2 where the specified confidence level is the security band).
- 9. As per claim 12, Goldenberg teaches the apparatus of claim 1 as described above.

 Goldenberg further teaches the apparatus wherein said output sets are a set of vectors (see page 3 paragraph 1 where the vectors are resolutions), each with three values: likelihood, trend indicator, and impact indicator, where the output sets are mapped from the state variable history at the study place (see figure 2 where the values are related to their normalized counts).

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10. As per claim 13, Goldenberg teaches the apparatus of claim 1 as described above. Goldenberg further teaches the apparatus wherein said rule system that governs the state transitions is the system with sets of logical rules, which evaluate both the logical and numerical functions to determine the system states and state transition (see page 2 paragraph 10 where the methodology encompasses a two-stage prediction system with both logical and numerical functions).

- 11. As per claim 14, Goldenberg teaches the apparatus of claim 1 as described above. Goldenberg further teaches the apparatus wherein said rule system that processes the structural components is a rule system with both logical and numerical functions mapping the structural components to supporting sets (see figure 2).
- 12. As per claim 15, Goldenberg teaches the apparatus of claim 12 as described above. Goldenberg further teaches the apparatus wherein said rule system that maps the state history to the output variables is a rule system with both logical and numerical functions mapping the state variables to the output variables. (see figure 2 where the output variables are the prediction).

Claim Rejections - 35 USC § 103

- 17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claim 8 is rejected under 103(a) as being unpatentable over Goldenberg et al., "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales" (see

reference U on the attached PTO-892) in view of Armstrong et al., "Updated Guidelines for Evaluating Public Health Surveillance Systems" (see reference V on the attached PTO-892).

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14. As per claim 8, Goldenberg teaches the apparatus of claim 7 as described above. Goldenberg does not explicitly teach the apparatus, wherein said set of state variables to model public health status at a specified place, comprises is healthy status, critical status, startingunusual status, upward-trend-unusual status, peak-unusual status, downward-trend status, and ending-unusual status. Armstrong teaches the apparatus wherein said set of state variables is healthy status (see page 7, Measures paragraph 2 where the healthy status is years of healthy life) critical status (see page 7, Measures paragraph 1 where the critical status is the indices of severity), starting-unusual status (see page 7, Measures paragraph 3 where preventability includes the detectability), upward-trend-unusual status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show trends), peak-unusual status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show trend changes), downward-trend status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show trends), and ending-unusual status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show ending).

It would be obvious to one of ordinary skill in the art at the time the invention was made to incorporate these features into Goldenberg. One of ordinary skill in the art would incorporate these features into Goldenberg with the motivation to better ensure the integration of surveillance and health information systems (see Armstrong page 3, Summary paragraph 1).

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Response to Arguments

18. Applicant's arguments, see actions 17 - 21, filed 4/27/2007, with respect to the rejection(s) of claim(s) 1 - 15 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 U.S.C. 112, second paragraph.

- 19. Applicant's arguments, see action 3, filed 4/27/2007, with respect to the rejection(s) of claim(s) 6 and 9 under 35 U.S.C. 112, 2nd paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 U.S.C. 102(b).
- 20. Applicant's arguments, see actions 4-6, filed 4/27/2007, with respect to Objections to the Claims have been fully considered and are persuasive. The Objections of claims 8, 10, 11 and 15 have been withdrawn.
- 21. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an apparatus) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- 22. Applicant's arguments filed 4/27/2007 have been fully considered but they are not persuasive. The arguments regarding 35 U.S.C. 101 do not overcome the lack of statutory matter within claims 1-15.
- 23. Applicant's arguments filed 4/27/2007 have been fully considered but they are not persuasive. The arguments regarding 35 U.S.C. 112, first paragraph do not overcome the lack of

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enablement and best mode as required. The original application does not include any physical device that would describe how one of ordinary skill in the art would make and use the invention.

- 24. In response to applicant's argument that the Golbenberg reference does not anticipate the current application, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
- 25. In response to applicant's argument that the Golbenberg in view of Armstrong references do not anticipate the current application, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
- 26. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lombardo et al., U.S. Pre-Grant Publication Number 2003/0009239 "METHOD AND SYSTEM FOR BIO-SURVEILLANCE DETECTION AND ALERTING"

Lombardo et al., U.S. Pre-Grant Publication Number 2004/0078146 "TECHNIQUES FOR EARLY DETECTION OF LOCALIZED EXPOSURE TO AN AGENT ACTIVE ON A BIOLOGICAL POPULATION"

28. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application

which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neal R. Sereboff whose telephone number is (571) 270-1373.

The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRS 6/5/2007

OURERVISORY PATENT EXAMINER